

APR 11 1997

510(k) SUMMARY

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DENTSPLY

NAME & ADDRESS:

DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
Fax (717) 854-2343
P. J. Lehn Telefax (717) 849-4343

K970123

CONTACT: P. Jeffery Lehn DATE PREPARED: January 10, 1997

TRADE NAME: DENTSPLY® CAVITRON® SPS SCALER SYSTEM

CLASSIFICATION NAME: Ultrasonic Scaler 21 CFR, 872.4850

PREDICATE DEVICE: CAVITRON® MODEL 3000™ ULTRASONIC SCALER K864996

DESCRIPTION: The SPS SCALER is a portable stand alone ultrasonic scaler. It operates with a fine, warm water spray, easily and effectively removing stubborn calculus and stains both supragingivally and subgingivally.

The SPS SCALER plugs into an ordinary electrical outlet and converts the 60 cycle AC house current into high frequency electro-mechanical vibrations. It consists of two parts: an electro-mechanical transducer and an electronic driving system. The electronic system incorporates two control loops: the first loop provides automatic frequency control driving each transducer at it's optimum operating frequency (nominally 30 kHz), while the second loop provides automatic stroke control to compensate for different transducer loading conditions. The SPS SCALER produces 30,000 microscopically small strokes each second at the transducer's tip. This, combined with acoustic effects of the coolant water, produces a synergistic action that sweeps away the heaviest calculus deposits while providing exceptional operator and patient comfort.

While the controls for the power and water flow of the SPS SCALER SYSTEM are located on the base unit, the on/off control used during operation is located on the foot pedal. When the foot pedal is pressed, the ultrasonic tip is activated and irrigation starts. The water from the irrigation system acts as both a cleaner and a coolant.

INTENDED USE: The SPS SCALER SYSTEM is designed for use in general prophylaxis and periodontal treatments and other areas of operative dentistry. This SPS SCALER SYSTEM is used with scaling tips and a fine warm water spray for debriding light to heavy calculus and plaque deposits from tooth and root surfaces.

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DENTSPLY® CAVITRON® SPS SCALER SYSTEM

TECHNOLOGICAL CHARACTERISTICS: The SPS SCALER SYSTEM is substantially equivalent to the predicate device, DENTSPLY's Cavitron Model 3000™ Ultrasonic Scaler (K864996), in intended use, as well as in design and construction. The basic technology, primary energy source, maximum electrical input power, maximum mechanical output energy, and base unit material are identical to the predicate device.

The SPS SCALER SYSTEM has the following enhancements: 1) a low power capability providing lower tip strokes than previously obtainable for periodontal applications and greater patient comfort; 2) a foot switch activated boost power mode which, when enabled, applies increased power to the handpiece; 3) a limited Automatic Gain Control circuit which automatically increases insert drive power, maintaining tip stroke under load; and 4) a smooth or appropriately textured, white base unit capable of withstanding common wipe disinfectants without discoloring or deteriorating.

The SPS SCALER meets DENTSPLY specifications. Underwriters' Laboratory conducted EMC testing on the SPS SCALER with positive results.

Results of in-house testing indicated that the SPS SCALER SYSTEM performed within stated specifications and was found to be as effective as the predicate device.

Results of SEM Analysis indicated that no significant qualitative difference was observed on the teeth following the use of the SPS SCALER SYSTEM compared to the predicate device.

We believe that the performance data and the testing reported above demonstrate the safety and effectiveness of the SPS SCALER SYSTEM for its intended use.

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